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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/207,168	12/07/1998	SHUJI HINUMA	48811	6431

7590

08/27/2002

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EXAMINER.

ROMEO, DAVID S

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 08/27/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/207,168

Applicant(s)

HINUMA ET AL.

Examiner

David S Romeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-19 and 21-37 is/are pending in the application.
- 4a) Of the above claim(s) 9-17,19,21-23 and 25-34 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5,7 and 18 is/are allowed.
- 6) ☒ Claim(s) 6,24, 35 and 36 is/are rejected.
- 7) ☒ Claim(s) 37 is/are objected to.
- 8) ☒ Claim(s) 1-7,9-19 and 21-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

The amendment filed May 24, 2002 (Paper No. 14) has been entered. Claims 1-7, 9-19, 21-37 are pending. Claims 9-17, 19, 21-23, 25-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and/or species, there
5 being no allowable generic or linking claim. Election was made without traverse in Paper No. 8. Claims 1-7, 18, 24, 35-37 are being examined to the extent that they read upon SEQ ID NOs: 1-7, 35-43. Any objection and/or rejection of record that is not maintained and/or repeated in this Office action is withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Any objection and/or rejection of record that is not
10 maintained and/or repeated in this Office action is withdrawn.

Newly submitted claims 35-37 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: newly submitted claims 35-37 are directed to or encompass SEQ ID NOs: 44-55, 57, 58, 60, 61. The invention originally
15 claimed is directed to SEQ ID NOs: 1-7, 35-43. The newly submitted claims 35-37 and the invention originally claimed are independent and distinct, wherein each is not required for the production or use of another, and wherein each can be manufactured independently of another.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution
20 on the merits. Accordingly, claims 35-37 are withdrawn from consideration to the extent that they are directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Maintained Formal Matters, Objections, and/or Rejections:

The application is not fully in compliance with the sequence rules, 37 C.F.R. § 1.821-

1.825. Applicants argue that the sequence listing as previously submitted is adequate and fully complies with the sequence rules. Applicants arguments have been fully considered but they are

5 not persuasive. The sequence rules embrace all unbranched nucleotide sequences with ten or more bases and all unbranched, non-D amino acid sequences with four or more amino acids, provided that there are at least 4 "specifically defined" nucleotides or amino acids. The rules apply to all sequences in a given application, whether claimed or not. All such sequences are relevant for the purposes of building a comprehensive database and properly assessing prior art.

10 It is therefore essential that all sequences, whether only disclosed or also claimed, be included in the database. Patent applications which contain disclosures of nucleotide and/or amino acid sequences must contain, as a separate part of the disclosure, a paper or compact disc copy (see § 1.52(e)) disclosing the nucleotide and/or amino acid sequences and associated information using the symbols and format in accordance with the requirements of §§ 1.822 and 1.823. Where the

15 description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of section 1.821, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO: " in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application. Specifically, the specification fails to recite the appropriate
20 sequence identifiers at each place where a sequence is discussed. See for example page 13. This is not meant to be an exhaustive list of places where the specification fails to recite the appropriate sequence identifiers at each place where a sequence is discussed. The specification

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has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. The application cannot issue until it is in compliance, i.e. until the specification recites the appropriate sequence identifier at each place where a sequence is discussed. Nucleic acid sequences with 10 or more nucleotides, at least 4 of which are specifically defined, must comply with the sequence rules. Amino acid sequences with 4 or more residues, at least 4 of which are specifically defined, must comply with the sequence rules. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as "residues 14 to 243 of SEQ ID NO:23" is permissible and the fragment need not be separately presented in the "Sequence Listing."

Correction is required.

Claim Rejections - 35 USC § 102

Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Andrews (CA, cited by Applicants). The rejection of record is applied to claim 35. Applicants argue that Andrews fails to teach the 12 amino acid sequence of SEQ ID NO: 43 having cortistatin or somatostatin activity. Applicants arguments have been fully considered but they are not persuasive. The structure of SS-37 is identical to the structure of the claimed polypeptide. A chemical composition and its properties are inseparable. It is further noted that Applicants are claiming in claim 7 similarly sized (SEQ ID NO: 4) and longer (SEQ ID NOs: 5-7) peptides having cortistatin or somatostatin activity. This is objective evidence that SS-37 has cortistatin or somatostatin activity. Therefore, the properties applicant discloses and/or claims, i.e. "cortistatin

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or somatostatin activity", are necessarily present in SS-37 in the absence of evidence to the contrary.

New formal matters, objections, and/or rejections:

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Claim Rejections - 35 USC § 112

The following claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10 Claim 24 recites the limitation "fragment peptide" in line 3. The antecedent basis for this limitation is unclear. It is unclear if a fragment of the peptide of claim 1, a fragment of the receptor, or any peptide fragment of any and all peptides is intended. The metes and bounds are not clearly set forth.

Claim Rejections - 35 USC § 102

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Claims 6, 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Andrews (CA, cited by Applicants). This rejection is being made in the event that evidence is provided that SS-37 does not have cortistatin or somatostatin activity. Andrews teaches SS-14, SS-34 (Abstract), and a minor form (31 residues) (page 15811, paragraph bridging left and right columns).

Applicants argue that Andrews fails to teach the 12 amino acid sequence of SEQ ID NO: 43
20 having cortistatin or somatostatin activity. Applicants arguments have been fully considered but they are not persuasive. The structure of SS-14, -34, and the minor 31 residue form are identical to the structure of the claimed polypeptide. A chemical composition and its properties are

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inseparable. It is further noted that Applicants are claiming in claim 7 similarly sized (SEQ ID NO: 4) and longer (SEQ ID NOs: 5-7) peptides having cortistatin or somatostatin activity. This is objective evidence that SS-14, -34, and the minor 31 residue form have cortistatin or somatostatin activity. Therefore, the properties applicant discloses and/or claims, i.e. "cortistatin or somatostatin activity", are necessarily present in SS-14, -34, and the minor 31 residue form in the absence of evidence to the contrary.

Claims 6, 35, 36 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sutcliffe (a15) in view of Sherman (u15).

Sutcliffe teaches a substantially isolated cortistatin protein and a cortistatin polypeptide including an amino acid residue sequence defining a cortistatin polypeptide having a sequence that corresponds to a sequence in the Sequence Listing selected from the group consisting of SEQ ID NOs 2, 5, 6, 7, 8, 9, 10, 11, 12, 23 and 24. The polypeptide can be synthetic, recombinant or a fusion protein. See column 2, lines 38-45. Sutcliffe's SEQ ID NO: 24 comprises the amino acid sequence of the present application's SEQ ID NO: 40 and SEQ ID NO: 43. The synthesis of all proteins from all living cells begins with methionine. See Sherman (u15), page 27, column 1, first sentence of introduction. Recombinant SEQ ID NO: 24, i.e., SEQ ID NO: 24 produced recombinantly, would comprise a methionine at the N-terminus. SEQ ID NO: 24 comprising a methionine at the N-terminus comprises the amino acid sequence of the present application's SEQ ID NO: 39 and SEQ ID NO: 42.

Alternatively, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to recombinantly express SEQ ID NO: 24 with a methionine at the N-

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terminus with a reasonable expectation of success. One of ordinary skill in the art would be motivated to recombinantly express SEQ ID NO: 24 with a methionine at the N-terminus because the synthesis of all proteins from all living cells begins with methionine. See Sherman (u15), page 27, column 1, first sentence of introduction.

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Conclusion

Claims 1-5, 7, 18 are allowable. Claims 6, 35-37 are objected to as containing non-elected subject matter.

10 ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

15 IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306

AFTER FINAL (703) 872-9307

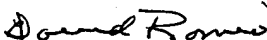
20 IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

25 ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

30


DAVID ROMEO
PRIMARY EXAMINER
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DSR
AUGUST 25, 2002